



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,920	02/07/2001	Jacques Dumas	BAYER 15 P3	6183

23599 7590 12/13/2007
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
----------	--------------

1625

MAIL DATE	DELIVERY MODE
-----------	---------------

12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/777,920	Applicant(s) DUMAS ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 9, 10, 12, 14-18, 25, 27, 29, 30, 34-37, 39, 40, 42 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 9, 10, 12, 14-18, 25, 27, 29, 30, 34-37, 39, 40, 42, 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

An action on the same follows.

Claims pending 2-5,9,10, 12, 14-18,25, 27, 29, 30,34-37, 39, 40, 42, 45-49.

Applicants have amended the claims to the elected group.

The rejection of the claims 2-5,9,10, 12, 14-18,25, 27, 29, 30,34, 37, 39, 40, 42, 45-49 under 35 USC 112 first paragraph scope of enablement still stands.

Even though applicants have deleted the Rx , Ry and Rz the Rx is still NRaRb which includes

R_x is R_2 or NR_6R_6 where R_3 and R_6 are,

a) independently hydrogen, or selected from the group consisting of C_1 - C_{10} alkyl, C_1 - C_{10} alkoxy, C_3 - C_{10} cycloalkyl, C_2 - C_{10} alkenyl, C_1 - C_{10} alkenoyl, C_6 - C_{12} aryl, C_3 - C_{12} hetaryl having 1-3 heteroatoms selected from O, N and S, C_3 - C_{12} cycloalkyl having 0-3 heteroatoms selected from N, S and O, C_7 - C_{24} aralkyl, C_7 - C_{24} alkaryl, substituted C_1 - C_{10} alkyl, substituted C_1 - C_{10} alkoxy, substituted C_3 - C_{10} cycloalkyl, having 0-3 heteroatoms selected from N, S and O, substituted C_6 - C_{12} aryl, substituted C_3 - C_{12} hetaryl having 1-3 heteroatoms selected from N, S and O, substituted C_7 - C_{24} aralkyl, substituted C_7 - C_{24} alkaryl, where R_4 and R_5 are a substituted group, they are substituted by halogen up to per halo, hydroxy, C_1 - C_{10} alkyl, C_3 - C_{12} cycloalkyl having 0-3 heteroatoms selected from O, S and N, C_3 - C_{12} hetaryl having 1-3 heteroatoms selected from N, S and O, C_1 - C_{10} alkoxy, C_6 - C_{12} aryl, C_1 - C_6 halo substituted alkyl up to per halo alkyl, C_6 - C_{12} halo substituted aryl up to per halo aryl, C_3 - C_{12} halo substituted cycloalkyl having 0-3 heteroatoms selected from N, S and O, up to per halo cycloalkyl, halo substituted C_3 - C_{12} hetaryl up to per halo hetaryl, halo substituted C_7 - C_{24} aralkyl up to per halo aralkyl or halo substituted C_7 - C_{24} alkaryl up to per halo alkaryl, or $C(O)R_6$.

W is independently selected from the group consisting of $-CN$, $-CO_2R^7$, $-C(O)NR^7R^7$, $-C(O)R^7$, $-NO_2$, $-OR^7$, $-SR^7$, $-NR^7R^7$, $-NR^7C(O)OR^7$, $-NR^7C(O)R^7$, C_1 - C_{10} alkyl, C_1 - C_{10} alkoxy, C_2 - C_{10} alkenyl, C_1 - C_{10} alkenoyl, C_3 - C_{10} cycloalkyl having 0-3 heteroatoms selected from O, S and N, C_6 - C_{14} aryl, C_7 - C_{24} alkaryl, C_7 - C_{24} aralkyl, C_3 - C_{12} heteroaryl having 1-3 heteroatoms selected from O, N and S, C_4 - C_{23} alkheteroaryl having 1-3 heteroatoms selected from O, N and S, substituted C_1 - C_{10} alkyl, substituted C_1 - C_{10} alkoxy, substituted C_2 - C_{10} alkenyl, substituted C_1 - C_{10} alkenoyl, substituted C_3 - C_{10} cycloalkyl having 0-3 heteroatoms selected from O, N and S, substituted C_6 - C_{12} aryl, substituted C_3 - C_{12} hetaryl having 1-3 heteroatoms selected

from O, N and S, substituted C₇-C₂₄ aralkyl, substituted C₇-C₂₄ alkaryl, and substituted C₄-C₂₃ alkheteroaryl having 1-3 heteroatoms selected from O, N and S;

each R⁷ is independently selected from H, C₁-C₁₀ alkyl, C₁-C₁₀ alkoxy, C₂-C₁₀ alkenyl, C₁-C₁₀ alkenoyl, C₃-C₁₀ cycloalkyl having 0-3 heteroatoms selected from O, S and N, C₆-C₁₄ aryl, C₃-C₁₃ hetaryl having 1-3 heteroatoms selected from O, N and S, C₇-C₁₄ alkaryl, C₇-C₂₄ aralkyl, C₄-C₂₃ alkheteroaryl having 1-3 heteroatoms selected from O, N and S, up to per-halosubstituted C₃-C₁₃ hetaryl having 1-3 heteroatoms selected from O, N and S, up to per-halosubstituted C₁-C₁₀ alkyl, up to per-halosubstituted C₃-C₁₀ cycloalkyl having 0-3 heteroatoms selected from O, N and S, up to per-halosubstituted C₆-C₁₄ aryl, up to per-halosubstituted C₇-C₂₄ aralkyl, up to per-halosubstituted C₇-C₂₄ alkaryl, and up to per-halosubstituted C₄-C₂₃ alkheteroaryl; and each Z is independently selected from the group consisting of -CN, -CO₂R⁷, -C(O)R⁷, -C(O)NR⁷R⁷, -NO₂, -OR⁷, -SR⁷, -NR⁷R⁷, -NR⁷C(O)OR⁷, -NR⁷C(O)R⁷, C₁-C₁₀ alkyl, C₁-C₁₀ alkoxy, C₂-C₁₀ alkenyl, C₁-C₁₀ alkenoyl, C₃-C₁₀ cycloalkyl having 0-3 heteroatoms selected from O, N and S, C₆-C₁₄ aryl, C₃-C₁₃ hetaryl having 1-3 heteroatoms selected from O, N and S, C₇-C₂₄ alkaryl, C₇-C₂₄ aralkyl, C₄-C₂₃ alkheteroaryl having 1-3 heteroatoms selected from O, N and S, substituted C₁-C₁₀ alkyl, substituted C₁-C₁₀ alkoxy, substituted C₂-C₁₀ alkenyl, substituted C₁-C₁₀ alkenoyl, substituted C₃-C₁₀ cycloalkyl having 0-3 heteroatoms selected from O, N and S, substituted C₆-C₁₂ aryl, substituted C₇-C₂₄ alkaryl, substituted C₇-C₂₄ aralkyl and substituted C₄-C₂₃ alkheteroaryl having 1-3 heteroatoms selected from O, N and S; wherein if Z is a substituted group, the one or more substituents are selected from the group consisting of -CN, -CO₂R⁷, -COR⁷, -C(O)NR⁷R⁷, -OR⁷, -SR⁷, -NO₂, -NR⁷R⁷, -NR⁷C(O)R⁷, and -NR⁷C(O)OR⁷.

As it can be seen from the above the terms have a very generic description with C₇-C₂₄ aralkyl, C₄-C₂₃- alkylheteroaryl, C₃-C₁₃ heteroaryl being some of them. The generic definition having 1-3 heteroatoms selected from N, O or S is also indefinite because with all the permutations and combinations it is not clear what the meets and bounds of the claims are.

Applicants argue that the Side Reactions is a general statement and has nothing to do with their compounds, this is incorrect. The Preface in the Side Reactions is the state of the Art indicating how difficult it is to synthesize compounds.

Also Pages 8 and 9 of the same book indicates how similar starting materials under same conditions give different products. This is the state of the art. Making compounds with different substituents is not simply putting everything together and expect that it would form similar compounds.

Examples of closely related starting materials which upon treatment with the same reagents yield completely different products are sketched in Scheme 1.6. The additional methyl group present in the second starting material slows addition to the carbonyl group of the radical formed by ring scission of the cyclobutane ring, and thus prevents ring expansion to the cyclohexanone. Removal of the methoxycarbonyl group leads to cleavage of a different bond of the cyclobutane ring and thereby again to a different type of product [12].

When the state of the art is so unpredictable, applicants need to provide much more guidance than just say that these generic substituent are within the scope of their compounds.

Only compound 104 and compounds in table 7 have been made on page 103.

In all the compounds Ra Rb are either a H or an alkyl.

None of the species made have any group other than that.

So with the amount of unpredictability in the art and limited amount of disclosure, it would certainly require an undue amount of burden to make and use these compounds.

Even though the Rx is drawn to one substituent NRaRb the definition of Ra and Rb is so vague with generic terms that it is impossible to decipher the full scope let alone make and use them.

With limited guidance of Ra and Rb being a H or an alkyl it would be burdensome and more than routine experimentation for one of skill in the art to make and use these compounds.

Applicants argue that

“The specification here provides both general and specific guidance for synthesizing the ureas claimed with over one hundred syntheses described on pages 56-80 and over 35 pages of specific synthesis steps that can be used to prepare the claimed compounds (pages 17-56), some with complex ring structures. There is no evidence this disclosure is lacking in any way. “

This is incorrect. Only one example C5 on page 56 which would fall within the elected group.

And in this compound, Ra and Rb are H and a methyl.

This one example does not commensurate with the scope of the claims.

Thus the rejection still stands.

Applicants claims 27, 29, 30, 35, 47, 48 are drawn to a method of treating that too a solid tumors /cancers. No data has been provided. An experiment according to Monica et al is stated on page 106, however no data has been provided.

The state of the art is that one drug cannot treat all the various cancers.

Yet without showing any data and any guidance applicants claim treating all tumors and cancers.

This is an undue amount of burden as it is not known that a drug can treat all cancers.

Conclusion

Claims 2-5,9,10, 12, 14-18,25, 27, 29, 30,34-37, 39, 40, 42, 45-49 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

RJ Desai
12/5/07

R.D.
December 5, 2007